Toxicology Database Management System

Overview

Background:

The National Toxicology Program (NTP) was established by the Secretary, Department of Health, Education and Welfare (now DHHS), in November 1978 as a department-wide effort to provide information about potentially toxic chemicals to regulatory and research agencies, and to strengthen the science base in toxicology. As part of NTP's effort to fulfill its mission, studies are conducted in vitro, and subchronic and chronic studies are conducted in rodents; these studies are done predominantly at contract laboratories which are monitored by NTP staff.

On an annual basis, NTP selects approximately 15-20 new chemicals for testing, has 35-40 subchronic studies and 60-75 chronic studies in different stages of testing and evaluation, and presents nearly 30 subchronic and chronic studies for public peer review. An additional 30 reproductive and developmental studies are also peer reviewed on a yearly basis. Computer systems have been developed to collect and manage data from these studies and files of the history and progress of each chemical study need to be maintained and made available for periodic reference.

The Toxicology Database Management System (TDMS) was developed by the NIEHS/NTP to allow staff scientists to monitor the conduct of in-life studies and manage data collected during the in-life and pathology portions of these studies.

TDMS consists of two components:

- The Laboratory Data Acquisition System (LDAS) (which runs on workstations located in the testing facilities) is a microcomputer application and hardware uniquely designed to directly collect in-life and pathology study data and to transmit this data to the TDMS database facility.
- The TDMS database and associated software (which runs on a LINUX server at the NIEHS computer facility) receives and manages the study data transmitted from the individual laboratories. Specifically designed software are used to generate reports for quality control and to help evaluate the progress and interpretation of study results.

Laboratory Data Acquisition System (LDAS)

LDAS was developed by the NIEHS/NTP to provide direct data collection of in-life and pathology data in testing labs and pathology facilities and to provide automated comunications between the study labs and the TDMS database. A total of 55 LDAS workstations are currently located in nine NTP contract laboratories in the US. LDAS I was developed in 1990-91 using IBM 386 workstations, C language applications, C-Scape forms and the Ingres database. LDAS I was retired in 1999.

LDAS II was developed in 1997-99 using Windows/NT. C++ is being used as the programming language and Crystal Report for LDAS II reports. Subversion is being used for configuration management. Oracle 8.1.7 is being used as the workstation database. The system now uses the Windows XP operating system. LDAS 3.0 is under development and will use open source reporting (Jasper) and database (PostGres) software.

There are three different types of LDAS workstations: Animal Room, Administrative and Pathology.

The Animal Room Workstation (ARWS) provides for the direct entry of in- life information such as body weights, food and water consumption, clinical observations and survival data. These data are collected in lab animal rooms according to an automated daily schedule which is downloaded from the TDMS according to individual study designs. The data are transferred via flash drives from each ARWS to the Administrative Workstation following each study's daily data collection. The animal room workstation is encased in a specialized enclosure which allows the technician to disinfect the entire workstation between animal rooms (See figure 1).

The Pathology Workstation (PWS) is used by pathologists to enter tumor and non-tumor histopathology observations as they evaluate slides. It may also be used to review animal removal data and notes and to define protocol required tissues for subchronic studies.

The Administrative Workstation (AW) is updated with data collected on the ARWS and PWS. Data transfer from the ARWS and PWS to the AW is accomplished via a flash drive. The AW contains the official copy of data for each study at the laboratory. The AW is used by the laboratory to communicate with the TDMS database at NIEHS to upload new data, to download studies and to view local reports.

Figure 1 Illustrates The Animal Room Workstation

Toxicology Database Management System (TDMS)

The TDMS was developed at NIEHS in the mid 1980's to manage NTP toxicology and carcinogenesis data and to provide standardized reports which are incorporated into the NTP Technical Reports. TDMS processes data by defining a standardized research protocol; managing a centralized database for archived files; employing rigorous data integrity procedures at the time of data capture; and providing access to tools for data retrieval, report generation, ad-hoc query and statistical analysis.

The TDMS database and its associated software reside on a LINUX Server at NIEHS. The TDMS database operates under the Oracle database management system using JAVA as the report language and SAS and JAVA for statistical analysis. The TDMS database currently has data on over 1,800 NTP studies stored in approximately 12 million records.

NIEHS scientists and laboratories can request over 50 different types of in-life and pathology reports, survival and growth curves and statistical analysis tables from the TDMS database. These reports are ordered via a Web application that runs on any browser and allows the user to view these reports via the Web or to print to one of over two dozen printers at NIEHS. In addition to these standardized study reports, hundreds of ad-hoc queries are performed via a Web-based query and special reports are also generated by NTP Information Center staff.

At the present time there are nine study laboratories performing NTP carcinogenesis and toxicity studies: Battelle Columbus, Battelle Northwest, Bioreliance, IIT Research Institute, ILS Laboratories, Pathology Associates, Southern Research Institute, the National Institutes of Environmental Health Sciences and the National Center for Toxicology Research.

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